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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,890	07/24/2006	Didier Courtois	112701-727	8593

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EXAMINER	
MACAULEY, SHERIDAN R	
ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
11/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/595,890	COURTOIS ET AL.	
	Examiner	Art Unit	
	SHERIDAN R. MACAULEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A response and amendment were received and entered on June 30, 2009. All evidence and arguments have been fully considered. Claim 5 is cancelled. New claims 12-17 have been added. Claims 1-4 and 6-17 are pending and examined on the merits in this office action.

Claim Rejections - 35 USC § 112

1. Rejections under 35 USC 112 have been withdrawn due to amendment.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-4 and 6-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hubbard (US 2005/0063250 A1; document cited in prior action) in view of Singh (US 6,190,913; document cited in prior action) and Martin (US 5,475,883). Claim 1 recites a cell culture apparatus comprising a flexible culture chamber, and a wave induction mechanism which is compatible with large scale up of a culture medium to an amount of at least 1000 L, the wave induction mechanism comprising: a plate that lifts up only a portion of the culture chamber, wherein the portion of the culture chamber lifted by the plate is between 5 and 50% of the length of the culture chamber. Claim 2 recites the cell culture apparatus according to claim 1, wherein the portion of the culture chamber lifted by the plate is between 8 and 20% of the length of the lower part of the culture chamber. Claim 3 recites the cell culture apparatus according to claim 1, wherein the wave induction mechanism lifts up part of the lower part of the culture chamber to an angle of 1 to 90 degrees with respect to the initial position of the plate. Claim 4 recites the cell culture apparatus according to claim 1, wherein the culture chamber comprises means to circulate air. Claim 6 recites the cell culture apparatus according to claim 1, wherein the culture chamber is a flexible plastic bag. Claim 7

recites the cell culture apparatus according to claim 1, wherein the culture chamber is filled from 10 to 80%. Claim 8 recites a method for cultivating plant cells, animal cells, or microorganisms, the method comprising providing a cell culture apparatus that comprises a flexible culture chamber, and a wave induction mechanism which is compatible with the large scale up of a culture medium to an amount of at least 1000 L, the wave induction mechanism comprising: a plate that lifts up only a portion of the culture chamber, wherein the portion of the culture chamber lifted by the plate is between 5 and 50% of the length of the culture chamber; and cultivating plant cells, animal cells, or microorganisms in the cell culture apparatus. Claim 9 recites a method for producing biomass cells, embryogenic plant cells, metabolites, secondary plant metabolites and/or recombinant molecules providing a cell culture apparatus that comprises a flexible culture chamber, and a wave induction mechanism which is compatible with the large scale up of a culture medium to an amount of at least 1000 L, the wave induction mechanism comprising: a plate that lifts up only a portion of the culture chamber, wherein the portion of the culture chamber lifted by the plate is between 5 and 50% of the length of the culture chamber; and growing biomass cells, embryogenic plant cells, metabolites, secondary plant metabolites and/or recombinant molecules in the cell culture apparatus. Claim 10 recites the cell culture apparatus according to claim 1 wherein the wave induction mechanism lifts up part of the lower part of the culture chamber to an angle of 1 to 25 degrees with respect to the initial position of the plate. Claim 11 recites the cell culture apparatus according to claim 1 wherein the culture chamber is filled from 20 to 40%. Claims 12-14 recite that the wave

induction mechanisms of claims 1, 8 and 9 comprise a motorized arm which raises the plate. Claims 15-17 recite that the plates of claims 1, 8 and 9 have a width equal to the width of the culture chamber and a length equal to between 5 and 50% of the length of the culture chamber.

6. Hubbard teaches a cell culture apparatus comprising a flexible culture chamber (i.e. a fermentor) and a wave induction mechanism (a bag that is capable of being selectively pressurized and deflated; abstract). Hubbard teaches that the wave induction mechanism may comprise a plate (p. 2, par. 38). Hubbard teaches that the wave induction mechanism may be located under a portion of the bag, and lifts between 5 and 50% of the bag shown in fig. 4 (p. 2, par. 34, fig. 4, p. 3, par. 51; note that from 8 to 20% of the bag may also be lifted in the apparatus as depicted by fig. 4). The bag shown in fig. 4 is lifted at an angle of between 1 and 90 degrees. Hubbard teaches that the culture chamber may be a flexible plastic bag and that the culture chamber comprises a means to circulate air (p. 2, par. 30, p. 3, par. 45). Hubbard teaches that the bags may be filled from 20 to 80% of the bag volume (p. 2, par. 29). Hubbard teaches that the apparatus may be used in a method for producing biomass cells, such as microorganisms (p. 2, par. 29). The reference does not specifically teach that the plate of the wave induction mechanism lifts the bag and does not teach the specific angles to which the chamber is lifted that are recited in the claims.

7. Singh teaches a cell culture apparatus comprising a flexible cell culture chamber (such as a plastic bag) and a wave induction mechanism (abstract, fig. 1). Singh teaches that the wave induction mechanism comprises a plate that has a pivot point

which alternately rocks each side of the cell culture chamber (col. 4, lines 7-17, fig. 1). Singh teaches that the wave induction mechanism moves the cell culture chamber between one and fifteen degrees (col. 4, lines 18-21).

8. Martin teaches a wave induction mechanism for a flexible, water-containing bag (a waterbed) comprising a plate and a mechanical arm, wherein the wave induction system lifts a portion at one end of the bag in which the wave is produced (see abstract, figs. 3-5).

9. At the time of the invention, a cell culture apparatus comprising nearly all of the claimed components was known, as taught by Hubbard. It was further known that similar cell culture apparatus could comprise a plate that lifts the culture chamber, as taught by Hubbard, and that wave induction mechanisms for fluid-filled containers could comprise a plate and an arm that lifts only a portion of the container. One of ordinary skill in the art would have been motivated to combine these teachings to modify the apparatus of Hubbard to use a plate that lifts the culture chamber because Singh teaches that a variety of lifting devices, such as plates, for lifting the culture chamber may be used in a similar cell culture apparatus (col. 4, lines 10-17). Martin teaches a wave induction mechanism for a fluid-filled bag wherein a plate lifts only a portion, which is between 5 and 50% of the container, as shown in figs. 3-5. One would thus have recognized that one wave induction mechanism could have been replaced by another in a similar apparatus with a reasonable expectation of success and that the inflatable bag of Hubbard could have been replaced by a lifting platform, such as those taught by Singh and Martin. Further, Singh teaches that the flexible culture bags can be used with

culture volumes up to 500 L; one of ordinary skill in the art would have recognized that this amount could have been varied in the course of routine experimentation to attain a method of cultivating volumes up to 1000 L. One of ordinary skill in the art would further have had a reasonable expectation of success in using a plate to lift the culture chamber in the mechanism of Hubbard because Hubbard teaches that such a plate is compatible with the system and Singh and Martin teach that lifting platforms may be used with flexible, fluid-filled chambers. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings cited above to arrive at the claimed invention.

10. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

Response to Arguments

11. Applicant's arguments filed June 30, 2009 have been fully considered but they are not persuasive. Applicant argues that the cited references do not teach all aspects of the claimed invention, specifically that the references do not teach various aspects of the claimed invention. In response to this, it noted that the features argued by applicant are taught by Martin, i.e., Martin teaches the use of a wave induction mechanism for a fluid-filled bag that lifts only a part of the bag and comprises a plate and mechanical arm. It would have been obvious to use such a wave induction mechanism in place of that taught by Hubbard for the reasons set forth above. Further, applicant argues that one of ordinary skill would not have been motivated to combine the teachings of

Hubbard and Singh because they are directed to the use different wave induction mechanism. However, both references are directed to the culture of biological materials in a flexible culture container. As discussed above, both references teach the use of multiple types of wave induction for such containers and one would therefore recognize that the teachings are relevant to each other and that the Martin reference could have been looked to for further types of wave induction mechanisms to use with a flexible, fluid-filled container. Although applicant further argues that one would not be motivated to combine the teachings of the prior art to arrive at the claimed method wherein culture volumes of 1000 L are used, it is noted that Singh teaches the use of large volumes. Further, although applicant argues that methods allowing for an increase in culture volume were unknown at the time of the invention because no system wherein the flexible culture chamber was lifted partially to induce wave motion, thereby generating less pressure in the chamber, it is noted that Hubbard and Martin teach such systems wherein only part of the chamber is lifted. Thus, this advantage was known in the art at the time of the invention. Therefore, applicant's arguments have been fully considered, but they are not found to be persuasive.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHERIDAN R. MACAULEY whose telephone number is (571)270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

SRM